Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2010733	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Skinpath Solutions	2000 Lake Park Drive, Se, Smyrna, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 14, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's manual, daily log sheets, and interview with the technical supervisor (TS), the lab failed to follow the reference range for Relative humidity (RH%) per the manufacturer's manual. Findings include: 1. Review of the 2023 processing room RH log sheets revealed the lab failed to ensure the recorded RH% was within acceptable limits of 30-85% for 36 of 255 days the lab was in operation. 2. Review of the 2024 processing room RH log sheets revealed the lab failed to ensure the recorded RH% was within acceptable limits of 30 - 85% for 72 of 255 days the lab was in operation. 2. Interview with TS #2 (CMS 209 form) on 1/14 /25 in the conference room at 2:00 PM, confirmed the aforementioned findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the manufacturer's manual, daily log sheets, and interview with the technical supervisor (TS), the labratory failed to document corrective actions when the relative humidity (RH%) was out of acceptable range. Findings include: 1. Review of the 2023 processing room RH log sheets revealed the lab failed to ensure the recorded RH% was within acceptable manufacurer limits of 30-85% for 36 of 255 days the lab was in operation. No documented corrective actions available. 2. Review of the 2024 processing room RH log sheets revealed the lab failed to ensure the recorded RH% was within acceptable manufacturer limits of 30 - 85% for 72 of 255 days the lab was in operation. No documented corrective actions available. 2. Interview with TS #2 (CMS 209 form) on 1/14/25 in the conference room at 2:00 PM, confirmed the aforementioned findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with a technical supervisor (TS), the laboratory director (LD) failed to ensure the testing personnel (TP) receive the appropriate training or demonstrated competency before performing patient testing. Findings include: 1. Review of personnel records (for the years of 2023- 2024) revealed the LD did not ensure the TP received proper lab training required to prior to the performance of patient testing. 2. . Review of personnel records (for the years of 2023- 2024) revealed the LD did not ensure the TP demonstrated competency required to perform patient testing. 3. Interview with TS #2 (CMS 209 form) on 01/14 /2025 at 1:30 PM in the conference room, confirmed the aforementioned findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment policy (SOP), competency records, and staff interview, the Technical Supervisor (TS) failed to include the six

	required competency assessment criteria when evaluating competency on testing personnel (TP). The findings include: 1. Review of testing personnel competency assessment records for 2023 and 2024 on 8 of 8 employees revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. Review of the SOP revealed the laboratory's competency policy only included: written microtomy competency assessment quiz, grossing skills and training check-off list, tech written competency assessment quiz, & written grossing competency assessment quiz. 3. Interview with TS # 2 (CMS 209) in the conference room on 1/14/25 at 1:45 PM confirmed competency assessments did not contain the six required competency assessment criteria.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with a technical supervisor (TS), the TS failed to perform semiannual competency on all testing personnel. Findings: 1. Review of the TP documents revealed the lack of semiannual competency evaluations for 8 of 8 high complexity TP. 2. Interview with TS #2 (CMS 209 form) on 1/14/25 in the conference room at 1:45 PM, confirmed the aforementioned findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with a technical supervisor (TS), the TS failed to perform annual competency evaluations on all testing personnel. Findings: 1. Review of the TP documents revealed the lack of annual competency evaluations for 8 of 8 high complexity TP. 2. Interview with TS #2 (CMS 209 form) on 1/14/25 in the conference room at 1:45 PM, confirmed the aforementioned findings.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

	This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP), daily log sheets, and an interview with the technical supervisor (TS), the laboratory testing personnel (TP) failed to follow the laborotaory procedure for logging the reagent changes for the Prisma Leica Stainer with Tissue- Tek Coverslipper. Findings: 1. Review of the SOP revealed the TP were to mark the reagents properly when logging the daily maintenence. A "key" is provided to distinguish how the reagents were handeled (R=rotated; C=changed; or A=added). 2. Review of the daily log sheets revealed the TP were not following the SOP for the years of 2023 or 2024. The "key" was not used, only lines or check marks were used. 3. Interview with TS #2 (CMS 209 form) on 1/14/25 in the conference room at 2:10 PM, confirmed the aforementioned findings.